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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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05/637,559 08/11/00 ZHENG

C 25436/1490

EXAMINER

HM12/0808

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PALMER & DODGE, LLP  
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NGUYEN, L. ART UNIT	PAPER NUMBER
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1635  
DATE MAILED:

08/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/637,550

Applicant(s)

ZHENG, CHAO-FENG

Examiner

Lauren Nguyen

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-26 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER  
PATENT ANALYST

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

*Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 24, drawn to a cell line comprising a stably integrated recombinant nucleic acid construct, classified in class 435, subclass 325, for example.
- II. Claims 10, 14, 15, 16, 25, and 26, drawn to a method of assaying for the activity of a signal transduction pathway, classified in class 435, subclass 6, for example.
- III. Claims 11-13, 14, 15, 16, 25, and 26, drawn to a method of screening for a modulator of the activation of a signal transduction pathway, classified in class 435, subclass 6, for example.
- IV. Claims 17, 21, 22, 23, 25, and 26, drawn to a method of assaying for the activation of a conditionally active transactivation domain of CHOP, classified in class 435, subclass 6, for example.
- V. Claims 18-20, 21, 22, 23, 25, and 26, drawn to a method of screening for a modulator of the activity of a conditionally active transactivation domain of CHOP, classified in class 435, subclass 6, for example.

Inventions II-V are distinct, each from the other, because each claimed process is materially different from the other comprising of materially different steps with materially different products. Additionally, each claimed process is drawn to different purposes and can be performed with products that are not shared by the other claimed processes.

Inventions II and IV are materially different from inventions III and V because inventions II and IV are drawn to methods of assaying and inventions III and V are drawn to methods of screening. A method of assaying comprises of steps to determine the presence, absence, or quantity of a particular substance whereas a method of screening comprises of steps to separate a large number of mixed substances into separate and different groups (Merriam-Webster's Collegiate Dictionary, Tenth Edition). These processes are materially different because steps within the method of assaying are not necessarily shared by the method of screening. Additionally, products used within the method of assaying are not necessarily used within the method of screening since the two methods are drawn to different purposes. For example, a method of assaying can comprise of an enzymatic reaction specific for a particular substance in the signaling pathway but a method of screening can comprise of a general enzymatic reaction that will catalyze a large class of substances and based upon whether or not enzymatic catalysis occurs or the extent of the enzymatic reaction, the identity of particular substances within the large class of substances screened will be further delineated, such as identification of a modulator of a signaling pathway. Furthermore, it is now routine practice in the art to use a high-throughput platform in methods of screening for more efficient analysis of extremely large pools of substances whereas adaptation of a high-throughput platform is not necessarily routine practice in methods of assaying for a particular substance within a signaling pathway, especially when the signaling cascade is not extensive, for instance. Moreover, Group II, drawn to a method of assaying for the activity of a signal transduction pathway, can be practiced, for instance, by assaying the final product of the signaling pathway via conjugation of the final product to a colorimetric enzyme hydrolysis reaction, for example, whereas Group III, drawn to

a method of screening for a modulator of the activation of a signal transduction pathway, can be practiced by assaying an intermediate or initial substrate but not the final product of the signaling cascade; hence, the target of the methods claimed in Groups II and III are different. Therefore, for the reasons given above for instance, examination of Groups II and IV would require an additional field of search from Groups III and V thereby creating an undue burden upon the Examiner.

Inventions II and III are materially different processes from inventions IV and V. Groups IV and V, drawn to methods of assaying and screening of a conditionally active transactivation domain of CHOP, would require an additional field of search from Groups II and III, drawn to methods of assaying and screening within a signal transduction pathway, since steps within the CHOP signaling pathway can be distinct from other known signaling pathway and such a search would create an undue burden upon the Examiner.

Inventions I and II-V are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the cell line comprising a stably integrated recombinant nucleic acid construct as claimed in Group I can be used in processes other than those claimed in Groups II-V and the processes claimed in Groups II-V can be practiced without the cell line claimed in Group I. For example, the cell line claimed in Group I can be used to produce the fusion protein recited in claim 1. Furthermore, the processes of Groups II-V can be

practiced with a colorimetric enzymatic assay to screen or assay for a substance within a signaling pathway, for instance.

Because these inventions are distinct for the reasons given above and an additional field of search would be required for each Group, restriction for examination purposes as indicated is proper.

A telephone call was made to Kathleen Williams on July 9 and July 17, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made. Instead, Applicant requested a written restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Nguyen, Ph.D. whose telephone number is 703-308-0256. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-7939 for After Final communications.

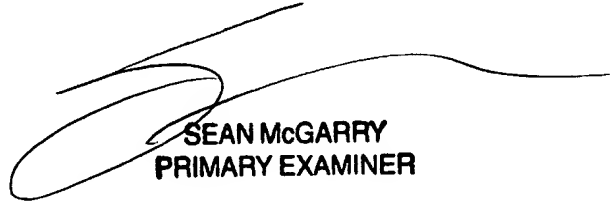
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lauren Nguyen, Ph.D.  
August 1, 2001



SEAN MCGARRY  
PRIMARY EXAMINER